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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,294	09/23/2003	James L. Hobart	SCI-00602	4649

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 11/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/669,294	Applicant(s) HOBART ET AL.	
	Examiner Michael Peffley	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-27, 29-31 and 48-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-27, 29-31 and 48-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicant's amendments and comments, received August 26, 2005, have been fully considered by the examiner. The following is a complete response to the August 26, 2005 communication.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-27 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vassiliadis et al (5,129,895) in view of the teachings of Colvard et al (5,738,677) and Adair (4,782,819).

Vassiliadis et al disclose a laser system comprising a laser source (9) for providing laser pulses, and a laser applicator (11) comprising an endoprobe (15) including an optical fiber (16) with an input end for receiving the laser pulses and an output end. A shielding member (28 or 37) is coupled to the endoprobe and protects tissue surrounding the target area to prevent treatment of non-intended tissues (see col. 4, lines 34+). Vassiliadis et al fail to disclose the use of a trunk optical fiber for coupling the laser source to the delivery optical fiber. Rather, a lens system (10) is used to couple the laser source to the delivery fiber. Vassiliadis et al also fail to disclose the particular use of laser bursts comprising laser pulses.

The examiner maintains that one of ordinary skill in the art is well aware that a fiber to fiber connection may be used to couple a probe to a laser source in lieu of the

Art Unit: 3739

use of a lens system as taught by Vassiliadis et al. Adair, as addressed in the previous Office action, teaches the use of a trunk fiber (98) for connecting a laser source to a delivery optical fiber (see Figure 8). The examiner maintains that this is an obvious and well-known alternative to the use of a lens system for coupling a laser source to a delivery fiber.

Regarding the use of laser bursts, Vassiliadis et al is silent with respect to the pulse characteristics of the laser source. However, Colvard et al, also addressed in the previous Office action, disclose the use of laser bursts having pulse parameters within those set forth by the applicant. The Colvard et al device is used for treating ocular tissue, just as the Vassiliadis et al device is used. The size of the fiber as set forth by Colvard et al (col. 8, lines 30-40) and the pulse energies, frequencies and durations (col. 7, lines 25-35) are all deemed to be parameters that would be obviously used in the Vassiliadis et al system, particularly since the Vassiliadis et al device is used in analogous procedures.

Finally, the examiner maintains that the various materials used in making optical fibers, such as sapphire and silica, are generally well known in the art and are obvious design considerations for one of ordinary skill in the art.

It is deemed to be an obvious modification for one of ordinary skill in the art to have used a trunk fiber to connect the Vassiliadis et al delivery fiber to a laser source in view of the teaching of Adai. To have further provided the Vassiliadis et al system with the particular laser pulse parameters as disclosed by Colvard et al for the treatment of ocular tissue would have been an obvious consideration for one of ordinary skill in the

Art Unit: 3739

art, particularly since the Colvard et al and Vassiliadis et al systems are used for analogous procedures.

Claims 48-63, 66 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over McMahon (5,413,555) in view of the teachings of Colvard et al (5,738,677) and Adair (4,782,819).

McMahon discloses a laser system that includes a laser source (inherent) and a flexible endoprobe (25) including a delivery optical fiber (35). The system includes a means (32) to adjust an approach angle of the optical fiber for treating tissue. The means to adjust is a pivoting member that allows the tubular probe to be aligned at a variety of angles by bending the pivoting member. The tubular probe includes a shield structure (34) extending from a front end of the firing portion of the fiber optic and blocks laser light from firing at any angle other than the preferred angle. McMahon fails to disclose the particular fiber optic dimensions, pulse characteristics, and the use of a trunk optical fiber for connecting the delivery fiber to the source.

The examiner maintains that one of ordinary skill in the art is well aware that a fiber to fiber connection may be used to couple a probe to a laser source. McMahon fails to show any specific connection between the laser source and the delivery fiber since such connections are generally very well known. Adair, as addressed previously, teaches the use of a trunk fiber (98) for connecting a laser source to a delivery optical fiber (see Figure 8). The examiner maintains that this is an obvious and well-known

Art Unit: 3739

means for coupling a laser source to a delivery fiber and would be obviously employed in the McMahon device.

Regarding the use of laser bursts, McMahon is silent with respect to the pulse characteristics of the laser source. However, Colvard et al, also previously addressed, disclose the use of laser bursts having pulse parameters within those set forth by the applicant. The Colvard et al device is used for treating ocular tissue, just as the McMahon device is used. The size of the fiber as set forth by Colvard et al (col. 8, lines 30-40) and the pulse energies, frequencies and durations (col. 7, lines 25-35) are all deemed to be parameters that would be obviously used in the McMahon system, particularly since the McMahon device is used in analogous procedures.

Finally, the examiner maintains that the various materials used in making optical fibers, such as sapphire and silica, are generally well known in the art and are obvious design considerations for one of ordinary skill in the art.

It is deemed to be an obvious modification for one of ordinary skill in the art to have used a trunk fiber to connect the McMahon delivery fiber to a laser source in view of the teaching of Adair. To have further provided the McMahon system with the particular laser pulse parameters as disclosed by Colvard et al for the treatment of ocular tissue would have been an obvious consideration for one of ordinary skill in the art, particularly since the Colvard et al and McMahon systems are used for analogous procedures.

Claims 48-53 and 57-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over McIntyre et al (5,549,601) in view of the teachings of Leckrone (4,685,458) and Adair (4,782,819).

McIntyre et al disclose a laser system comprising a flexible endoprobe (11) coupled to a laser source (15). The system includes a steering means to adjust the approach angle of the delivery optical fiber (see 3 and col. 3, lines 57-60). The endoprobe includes a flexible guide (17) that is bendable (Figure 3) and the delivery fiber (12) is extendable from the guide. McIntyre et al fail to disclose the particular connection between the delivery fiber (12) and the source (i.e. they fail to disclose a "trunk" fiber), and also fail to disclose the particular pulse characteristics for the laser beam (i.e. use of bursts, pulse durations, etc.).

Again, the examiner maintains that the use of a fiber to fiber connection between the laser source and a delivery optical fiber is very well known in the art and fairly taught by Adair. To have used such a fiber connection to connect the delivery fiber to the laser source would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Adair.

With regard to the use of pulse bursts, Leckrone discloses a similar laser catheter and specifically teach the use of pulse bursts (col. 6, lines 48-52). The examiner maintains that the specific pulse duration, repetition rate, etc. would be obvious design considerations for one of ordinary skill in the art and are fairly suggested in the cited prior art. Similarly, the use of sapphire and/or silica optical fibers is

Art Unit: 3739

generally well-known in the art, and the specific size of the fiber(s) would be an obvious design consideration for one of ordinary skill in the art.

To have provided the McIntyre et al system with a laser source that provides laser "bursts" to treat tissue would have been an obvious consideration for one of ordinary skill in the art since Leckrone teaches of the use of laser bursts to treat tissue. As addressed previously, the use of a "trunk" fiber for connecting the delivery fiber to a laser source is deemed an obvious design consideration in view of the teaching of Adair.

Response to Arguments

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Abela et al (5,061,265) discloses a side-fire catheter device with a shield member surrounding the optical fiber, and Khoury (5,217,454) disclose a laser catheter device with a means to adjust the delivery angle of the fiber optic.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

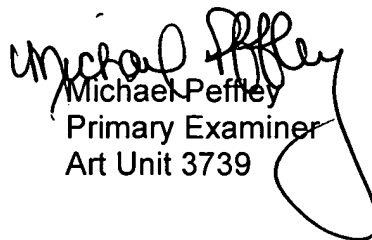
Art Unit: 3739

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Peffley
Primary Examiner
Art Unit 3739

mp
November 7, 2005